Section 5: 510(k) Summary

K073651
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Device Information

Category	Comments
Sponsor:	NeoTract, Inc. 4473 Willow Rd., Suite 100 Pleasanton, CA 94588 Tel: 925 401 0700 Fax: 925 401 0699
Correspondent Contact Information:	Suzan Moser NeoTract, Inc. 4473 Willow Rd., Suite 100 Pleasanton, CA 94588 Tel: 925 401 0627 Fax: 925 401 0667
Device Common Name:	Surgical Suture
Device Classification & Codes:	Class II, GAT, GDW
Device Classification Name:	Nonabsorbable Poly(ethylene Terephthalate) Surgical Suture
Device Proprietary Name:	NeoTract Anchor System

Predicate Device Information

Predicate Devices:	NeoTract Anchor
Predicate Device Manufacturer:	NeoTract, Inc.
Predicate Device Common Name:	Surgical Suture
Predicate Device Classification:	Nonabsorbable Polypropylene Surgical Suture
Predicate Device Classification & Codes:	Class II, GAW, GDW

Date Summary Prepared

December 21, 2007

Description of Device

The NeoTract Anchor System consists of a single use delivery device that delivers up to two permanently implantable NeoTract Anchors. A NeoTract Anchor consists of one nitinol tube connected by nonabsorbable monofilament suture to a stainless steel pin with locking ring.

Intended Use

The NeoTract Anchor System is intended for the approximation of soft tissue in open surgical procedures.

Comparison to Predicate Device
The NeoTract Anchor System is substantially equivalent to the predicate device, NeoTract Anchor, K061700, in Indications for Use, Class, Principal Operator, Use Location, Operating Principle, Design, How Shipped, Reuse, and Sterilization Method.

The testing described below demonstrates that differences in the devices do not raise any issues of safety or effectiveness.

NeoTract concludes that the devices are substantially equivalent.

Summary of Supporting Data
Biocompatibility testing results demonstrate that the device is in compliance with ISO 10993-1:2003 – Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing.

Bench testing results demonstrate that the device is in compliance with USP 30:2007; Class II Special Controls Guidance Document Surgical Sutures; Guidance for Industry and FDA; the medical community expectations and the product labeling. Bench testing results also demonstrate that the device performance is substantially equivalent to the predicate device, the NeoTract Anchor (K061700).

Animal testing results further demonstrate that the device does not present any issues of safety or effectiveness in relation to its predicate, the NeoTract Anchor (K061700).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2008

Neotract, Incorporated
% Ms. Suzan Moser
Vice President, Clinical
and Regulatory Affairs
4473 Willow Road, Suite 100
Pleasanton, California 94588

Re: K073651
Trade/Device Name: NEOTRACT Anchor System
Regulation Number: 21 CFR 878.5000, 21 CFR 878.4750
Regulation Name: Nonabsorbable polyamide surgical suture, Implantable staple.
Regulatory Class: Class II
Product Code: GAT, GDW
Dated: December 21, 2007
Received: December 26, 2007

Dear Ms. Moser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: This application K073651

Device Name: NEOTRACT Anchor System

Indications For Use: The NeoTract Anchor System is intended for the approximation of soft tissue in open surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073651